

Department of Health and Human Services

National Human Research Protections Advisory Committee (NHRPAC) Meeting
Wednesday, December 20th & Thursday December 21st 2000

Pooks Hill Marriott, Bethesda
5151 Pooks Hill Road

AGENDA

Wednesday, December 20, 2000

8:30am – 9:00am	Coffee & Conversation Opportunity for Members to meet each other	[30 minutes]
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9:00am – 9:30am	Welcome and Introductions: <i>Greg Koski, M.D., Ph.D.,</i> <i>Executive Secretary of NHRPAC;</i> <i>Chairperson, Human Subjects Research</i> <i>Subcommittee, Committee on Science,</i> <i>National Science and Technology Council;</i> <i>Director, Office of Human Research</i> <i>Protection</i>	[10 minutes]
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<i>Kate-Louise Gottfried, J.D., M.S.P.H.</i> <i>Executive Director, NHRPAC</i>	[5 minutes]
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<i>Mary Faith Marshall, Ph.D</i> <i>Chairperson, NHRPAC</i>	[10 minutes]
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9:30am – 9:45am	Swearing in of Committee: Program Support Center Personnel Specialist <i>Jackie Coleman</i>	[15 minutes]
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9:45am – 10:00am	Charge to the Committee: <i>The Honorable Donna E. Shalala,</i> <i>Secretary of Health and Human Services</i> (Invited)	[15 minutes]
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The Honorable Edward M. Kennedy
Senator of Massachusetts

10:00am – 11:15am	<i>Committee Members</i> (5 minutes apiece) Brief comments about yourself areas of particular concern	[75 minutes]
[10:30am – 10:45am]	BREAK	[15 minutes]
11:15am – 12:45pm	Institutional Review and Oversight of Non-Biomedical Research Under the Common Rule: <i>Felice J. Levine, Ph.D.</i> <i>Executive Officer</i> <i>American Sociological Association</i>	[1 hour, 30 minutes] [20 minutes]
[11:35pm – 12:15pm]	Discussion	[40 minutes]
[12:15pm – 12:45pm]	Recommendations	[30 minutes]
12:45pm -- 1:45pm	LUNCH - On your own	
1:45pm – 4:00pm	Financial Relationships in Human Research: <i>Stuart L. Nightingale, M.D.,</i> <i>Senior Medical Advisor to the</i> <i>Assistant Secretary for Planning & Evaluation</i>	[2 hours, 15 minutes] [15 minutes]
[2:00pm – 3:30pm]	Discussion	[1 ½ hours]
[3:30pm – 4:00pm]	Recommendations	[30 minutes]
4:00pm – 4:30pm	General Discussion Recap of Day 1	[30 minutes]
4:30pm	THANK YOU – ADJOURN	
4:30pm – 6:00pm	<i>Reception, Hosted by:</i> <i>David Satcher, M.D., Ph.D.</i> <i>Assistant Secretary for Health and</i> <i>Surgeon General</i> [BY INVITATION ONLY]	<i>Pooks Hill Marriott</i>

Thursday, December 21: 9:00am – 4:00pm

9:00am – 9:30am	Brief Recap of Previous Day's Discussion [30 minutes] Other Issues that Occurred Outside the Meeting: <i>Mary Faith Marshall, Ph.D</i>	
9:30am – 11:30am	Declaration of Helsinki: <i>Dixie E. Snider, M.D., M.P.H.</i> <i>Associate Director of Science</i> <i>Centers for Disease Control and Prevention</i>	[2 hours] [15 minutes]
[9:45am – 11:00am]	Discussion	[1 hour]
[10:30am – 10:45am]	BREAK	
[11:00am – 11:30am]	Recommendations	[30 minutes]
11:30am – 12:30pm	Research Involving Children: <i>Alan Fleischman, M.D.</i> <i>Senior Vice President, NY Academy of Medicine</i> <i>Clinical Professor of Pediatrics and Clinical Professor</i> <i>of Epidemiology & Social Medicine, Albert Einstein</i> <i>College, New York</i>	[20 minutes]
12:30pm – 1:30pm	LUNCH – On your own	
1:30pm – 3:30pm	Research Involving Children <i>Discussion Continued</i>	[2 hours]
[3:00pm – 3:30pm]	Recommendations	
3:30pm – 4:00pm	Recap of the Meeting & Future Actions	[30 minutes]
4:00pm	THANK YOU – ADJOURN	